

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

Mitsubishi Chemical Corporation,) Civil Action No. 07 CV 11614
Mitsubishi Tanabe Pharma Corporation,)
Encysive Pharmaceuticals Inc., Glaxo Group) **Electronically Filed**
Limited, and SmithKline Beecham plc,)
) Hon. Judge Koeltl
Plaintiffs,)
)
v.)
)
Barr Laboratories, Inc. and)
Pliva-Hrvatska d.o.o.)
)
)
Defendants.)

**GLAXO GROUP LIMITED'S AND SMITHKLINE BEECHAM PLC'S
REPLY MEMORANDUM IN SUPPORT OF
MOTION FOR LEAVE TO FILE A SECOND AMENDED COMPLAINT**

Plaintiffs Glaxo Group Limited and SmithKline Beecham plc (together “GSK”) submit this Reply Memorandum in support of their Motion for Leave to File a Second Amended Complaint adding a third GSK entity, SmithKline Beecham Corp. (“SKB Corp.”), as a named plaintiff in this patent infringement case. SKB Corp. holds an exclusive license under the patent-in-suit and is the exclusive United States distributor of Argatroban Injection, the commercial embodiment of the patent-in-suit. Consequently, SKB Corp. is a proper party to this lawsuit.

I. INTRODUCTION

Defendants Barr Laboratories, Inc. and Pliva-Hrvatska d.o.o. (together, “Barr” or “Defendants”) do not dispute that SKB Corp. is an exclusive licensee with standing to enforce the patent-in-suit.¹ Instead, Barr asserts that the proposed amendment is futile because SKB

¹ On March 12, 2008, GSK provided Barr with copies of licensing agreements establishing that SKB Corp. is an exclusive licensee of the patent-in-suit.

Corp.'s lack of standing at the time the original and first amended complaints were filed in this case is a "defect[]" that "cannot be cured retroactively." Defendants' Opposition to GSK's Motion for Leave to File a Second Amended Complaint ("Defs. Opp.") at 1. Barr's argument (and the caselaw cited in support) are inapplicable because they concern situations in which a party seeks to rectify a situation in which *no* plaintiff possessed standing at the time a patent infringement suit was filed. In those situations, courts have held that the lack of any party with standing at the outset of a patent infringement case is a jurisdictional "defect" that cannot be "cured" retroactively.

This case is different. Here, the current plaintiffs, Mitsubishi, Encysive, and GSK *did* have standing at the time of filing of the amended complaint. GSK seeks to add another plaintiff (SKB Corp.), which did not have standing at the time the First Amended Complaint was filed, but indisputably has standing now. Thus, the proposed amendment to add SKB Corp. does not cure any jurisdictional "defect" nor is it "retroactive." Indeed, substantial authority makes clear that joinder of an exclusive licensee as a plaintiff in ongoing patent litigation is proper, even if the licensee's rights in the patent were obtained after the filing of the complaint.

Barr also contends that it will be "prejudiced" by the proposed amendment because SKB Corp., the entity that distributes the product at issue in this case, may seek injunctive relief or damages for Barr's patent infringement. But that type of prejudice does not warrant denial of a motion for leave to amend the pleadings; indeed most amendments to pleadings include some type of a claim against the opposing party. Not surprisingly, Barr fails to cite a single case in which leave to amend was denied for prejudice of this sort. Moreover, Barr concedes that SKB Corp. would have standing to bring a separate action for patent infringement. Defs. Opp. at 12.

Thus, Defendants' request for the Court to deny leave would not avoid any alleged "prejudice," but would simply result in unnecessary and inefficiently duplicative patent infringement actions.

Because Defendants have not met the heavy burden required to overcome the presumption that leave to amend should be "freely granted," and SKB Corp. is a proper party to this lawsuit, GSK's Motion should be allowed.

II. ARGUMENT

A. GSK's Motion to Amend is Not an Attempt to Retroactively "Cure" a Standing "Defect"

Standing is a "threshold" question (Defs. Opp. at 4) because it is a jurisdictional requirement that must be satisfied before a court may even hear a case. *See, e.g., Lewis v. Casey*, 518 U.S. 343, 349 n.1 (1996) (Under Article III, standing "is jurisdictional and not subject to waiver."). *See also Enzo APA & Son, Inc., v. Geapag A.G.*, 134 F.3d 1090, 1094 (Fed. Cir. 1998) ("Having found Geapag to be without standing for failing to join the patentee, it follows that the court *lacks jurisdiction over Enzo's declaratory judgment claims* under Fed. R. Civ. P. 19 for nonjoinder.") (emphasis added). Accordingly, at the time a patent infringement claim is filed, a plaintiff must have standing; a *nunc pro tunc* assignment may not confer retroactive standing on a plaintiff who had no standing at the time the litigation was filed. *Id.* at 1093-1094. This rule stems, in part, from a desire to promote judicial economy by avoiding the "premature initiation of [a]n action" by a party without rights to the patent-in-suit. *Id.* at 1093.

In this case, GSK's proposed addition of SKB Corp. as a plaintiff is not an effort to confer standing "retroactively" or to cure any defect in standing. Mitsubishi, the assignee of all substantial interest in the patent-in-suit, as well as three exclusive licensees, Encysive, Glaxo Group Limited and SKB plc, are already parties. Thus, there is no standing "defect" to cure.

Rather, GSK seeks to join SKB Corp., which became an exclusive licensee after the First Amended Complaint was filed and now has a cognizable interest in the litigation.

Defendants never come to terms with the facts of this particular case, in which the present plaintiffs indisputably have standing and merely seek to join an exclusive licensee that acquired standing after the original complaint was filed. Under such circumstances, it is well established that an exclusive licensee may be joined as a plaintiff in an infringement suit after the lawsuit has been filed. *See, e.g., Kalman v. Berlyn Corp.*, 914 F.2d 1473, 1480 (Fed. Cir. 1990) (reversing as abuse of discretion district court's decision to deny post-filing joinder of exclusive licensee). It is also well established that a party that lacks standing at the time of filing of the original complaint but subsequently acquires sufficient rights in the patent to obtain standing may be joined at any time prior to the entry of judgment. *See, e.g., Insituform Techs., Inc. v. CAT Contracting, Inc.*, 385 F.3d 1360, 1372 (Fed. Cir. 2004) (permitting joinder of patent assignee with original plaintiff where assignee, a subsidiary of plaintiff, obtained its rights in the patent after trial but before judgment); *Randolph-Rand Corp. of New York v. Shafmaster Co., Inc.*, No. CIV 97-44-M, 1999 WL 814367, at *2 (D.N.H. Apr. 8, 1999) (rejecting defendant's attempt to dismiss exclusive licensee that had acquired rights in patent after filing of litigation).

Defendants do not acknowledge these precedents, but instead argue as if this is a situation in which SKB Corp. was the only plaintiff in the instant litigation, and attempted to remedy a defect in standing by entering into a license agreement designed to confer standing retroactively. Defs. Opp. at 4-8. The cases that Defendants cite are therefore distinguishable. In each of the cited cases, the Court determined that *no named plaintiff* had standing when the lawsuit was brought, and therefore the court never had jurisdiction and had to dismiss the case. Defs. Opp. at

5-7 (Section III.A.2).² This was true in *Enzo*, upon which Defendants heavily rely, which involved a retroactive attempt to confer standing where *none* of the initial plaintiffs had standing. 134 F.3d at 1094.

Here, however, the current plaintiffs do have standing, and thus the holding in *Enzo* and the other cases cited by Barr do not apply. *See Gipson v. Maddox*, 511 F. Supp. 2d 1182, 1191 (S.D. Ala. 2007) (rejecting challenge to standing based on *Enzo* where, as here, at least one original plaintiff had standing: “The circumstances present here are markedly different than the parade of horrors that motivated the *Enzo* ruling. Unlike in *Enzo*, here the Complaint always included ... [an entity that] unquestionably had standing to sue Mattox at that time. This is not a case in which suit was filed prematurely by plaintiffs who lacked standing.”).

B. Defendants Have Not Demonstrated Undue Delay, Bad Faith, or Prejudice

Defendants have not demonstrated that GSK’s request to join SKB Corp. as a plaintiff is made in bad faith or will result in undue delay or prejudice.

Barr’s assertion that the addition of proposed amendment would prejudice them by “affect[ing] the calculus” regarding damages and injunctive relief (Defs. Opp. at 9) misses the mark. Defendants cite no authority for this proposition, which is understandable: the joinder of an additional plaintiff with an interest in the litigation will affect the “calculus” of damages and injunctive relief in almost every case. Thus, under Defendants’ conception of alleged “prejudice,” joinder under Rule 21 and amendments under Rule 15 would almost always be improper, yet it is plain from the weight of authority that the opposite is true. Speculation as to whether the joinder of SKB Corp. would affect a subsequent analysis of remedies is not

² *See Paradise Creations, Inc. v. UV Sales, Inc.*, 315 F.3d 1304 (Fed. Cir. 2003) (no original plaintiff had standing at time of filing); *GAIA Tech., Inc. v. Reconversion Techs., Inc.*, 93 F.3d 774 (Fed. Cir. 1996), *as amended on reh’g*, 104 F.3d 1296 (Fed. Cir. 1996) (same); *Quiedan Co. v. Central Valley Builders Supply Co.*, No. C 92-3532 BAC, 1993 WL 451503 (N.D. Cal. Oct. 28, 1993), *aff’d*, 31 F.3d 1178 (Fed. Cir. 1994) (same); *Afros S.p.A v. Krauss-Maffei Corp.*, 671 F. Supp. 1402 (D. Del. 1987), *aff’d*, 848 F.2d 1244 (Fed. Cir. 1988) (same); *Multistack LLC v. ArcticHill Inc.*, No. 05-CIV-3865 (PAC), 2006 WL 510506 (S.D.N.Y. Mar. 1, 2006) (same).

prejudice of any kind, let alone cognizable prejudice sufficient under Rules 15 and 21 to deny leave to amend and to join SKB Corp.

Barr also suggests that GSK's only remedy is to dismiss the instant action and file another suit naming SKB Corp. as a party, and that Plaintiffs are unwilling to do so for fear of forfeiting the automatic 30-month regulatory stay of Defendants' ANDA. Defs. Opp. at 12. This argument is incorrect. Those GSK parties with standing to sue are already named Plaintiffs on the First Amended Complaint, which was filed well within the permissible time period after receiving Defendants' Paragraph IV notification. Dismissal of the present action is therefore neither necessary nor appropriate.

Similarly, while Barr makes passing reference to GSK's "substantial delay" in filing its motion for leave to amend (Defs. Opp. at 13), it is undisputed that GSK filed its Motion for Leave to Amend on February 29, 2008, nearly two weeks before Defendants filed their Answer on March 12, 2008. At the time of the proposed amendment, the parties had yet to appear before the Court for an initial scheduling conference, and discovery had not yet begun. No undue delay has occurred.

Finally, Defendants assert that GSK's proposed amendment should be denied as a punishment of sorts for GSK's alleged (but unspecified) "strategic choices." Defs. Opp. at .11. This argument does not identify any potential prejudice to Defendants and, in any event, lacks any record support. At the time of filing of the action, GSK mistakenly, but reasonably, believed that SKB Corp. was an exclusive licensee. *See, e.g., Enzo*, 134 F.3d at 1093 (terms of a license can be implied based on course of conduct). Upon discovering documentation indicating that the license to SKB Corp. was non-exclusive, GSK dropped SKB Corp. from the case because current Federal Circuit authority holds that non-exclusive licensees do not have standing to sue.

See Intellectual Prop. Dev., Inc. v. TCI Cablevision of Cal., Inc., 248 F.3d 1333, 1345 (Fed. Cir. 2001). GSK expeditiously prepared a written exclusive license, and sought leave to amend before any delay or prejudice could possibly result. Notably, the Federal Circuit has permitted amendment to join assignees and exclusive licensees even where the motion was filed two years after trial, *e.g.*, *Insituform Technologies, Inc.*, 385 F.3d at 1371-72, and has reversed, as abuse of discretion, a decision to deny a motion to amend that was filed after trial, *e.g.*, *Kalman*, 914 F.2d at 1480. In view of *Insituform* and *Kalman*, Barr's argument that the proposed Second Amended Complaint would result in undue delay or prejudice is simply untenable.

III. CONCLUSION

For the reasons set forth above and in GSK's opening brief, GSK respectfully requests that the Court grant the Motion for Leave to File a Second Amended Complaint.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Christopher R. Noyes, an attorney at law admitted *pro hac vice* to practice before this Court, certify that on this 21st day of March, 2008, I caused to be served via ECF Glaxo Group Limited's and SmithKline Beecham plc's Reply Memorandum in Support of Motion for Leave to File a Second Amended Complaint on all counsel of record.

/s/ Christopher R. Noyes.
Christopher R. Noyes, Esq.